

REMARKS

Amended Claim 1 and Claims 2-4, 6-15 remain in the Application.

The Examiner has rejected Claim 14 again under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner indicates that the claim is rejected based on the previous Office Action. The previous Office Action stated that Claim 14 contained subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. Applicant respectfully submits that this is not the case. Applicant respectfully submits that the Examiner bears the burden of providing the *prima facie* case to support the rejection of the application and therefore the Examiner has the burden of showing that the application is non-enabling. As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of Section 112, the "Patent Office" bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. (See *In re Wright* 999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

Furthermore, as stated *In re Moore* 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971), the CCPA summarized the general requirements for enabling disclosure:

The relevant inquiry may be summed up as being whether the scope of enablement provided to one of ordinary skill in the art by the disclosure is such as to be commensurate with the scope of protection sought by the claims.

Furthermore, as stated by the Federal Circuit in *Fiers v. Sugano*, 984 F.2d 1164, 25 USPQ2d 1601, 1607 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of Section 112, the "Patent Office" bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. (See *In re Wright* 999 F.2d 1557, 27 USPQ2d 1510, 1530 (Federal Circuit 1993)).

Furthermore, as stated by the C.C.P.A. *In re Angstadt*, 537 F.2d 498, 190 USPQ 214, 219 (C.C.P.A. 1976):

We note that the PTO has the burden of giving reasons, supported by the record as a whole, why the specification is not enabling ... Showing that the disclosure entails undue experimentation is part of the PTO's initial burden ...

The enablement requirement, however, does not require that the Applicant disclose the invention in a manner that can be understood by everyone. If such were the case patent applications would be long, unfocussed documents. The CCPA has also stated that

"not every last detail is to be described, else patent specifications would turn into production specifications which they were never intended to be" (see *In re Gay*, 309 F.2d 769, 135 USPQ 311, 316 (C.C.P.A. 1962).

Furthermore, the public would also likely have difficulty in determining the new or important aspects of the invention since the issued patent would contain much extraneous information. Rather, for an application to be enabling it must explain how to make and use an invention to one of ordinary skill in the art. Again, the person of ordinary skill is fictitious. The Federal Circuit has also commented:

The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative. The factors that may be considered in determining level of skill include type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology and educational level of active workers in the field. Not all such factors may be present in every case and one or more of them may predominate. (See *Custom Accessories Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986))

Thus, "it is irrelevant whether the specification explains how to make and use the invention using broad terminology or illustrative examples." (See *In re Wright*, 9999 F.2d 1557, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Therefore Applicant respectfully submits that a person skilled in the art would know how to carry out Claim 14 and would know all the known forms of torsemide prior to the filing date of this application. See, for example, United States Patent No. 6,465,496 and United States Patent No. 6,670,478, as well as the references cited therein. The various forms of torsemide were known at the filing date of the application.

Furthermore, as explained by the Federal Circuit, the specification need not describe or enable the application to a lay person, rather need only describe the invention to one of ordinary skill in the art. (See *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 56 USPQ2d 1332, 1336 (Fed. Cir. 2000)) Therefore, also as found in *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1584, 39 USPQ2d 1573, 1578-79:

Prior art references may be indicative of what all those skilled in the art generally believe a certain term means ... [and] can often help to demonstrate how a disputed term is used by those skilled in the art.

Therefore, the interpretation of the same or similar claim terminology in the prior art may be used in determining what one of ordinary skill in the art would have understood the patent disclosures to teach with respect to the enablement requirement. See also *In re Cortright*, 165 F.3d, 1353, 49 USPQ2d 1464 (Fed. Cir. 1999) in which the prior art understanding of terminology used in the patent claims was used to determine that the claimed invention was in fact enabled by the patent application disclosure. Therefore, reconsideration of Claim 14 is respectfully requested.

The Examiner has also rejected Claims 1, 2, 6-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant, first of all, acknowledges that the rejection with respect to the terms I and II have been withdrawn and the objection to Claim 5 has been rendered moot by Applicant's cancellation of Claim 5. In light of that the only rejections remaining in respect of Claims 1, 2, 6-14 is the phrase "if desired" in Claim 1 and Claim 2 and 6-14 as they depend on Claim 1, as well as the phrase "polymorphs" in Claim 14. Application respectfully submits that the term "polymorphs" was cancelled in the previous response dated December 10, 2004 and substituted with the term "forms". This term is supported in the application as originally filed at paragraph [0019], lines 9-11 and also would be understood by persons skilled in the art as defined in the prior art, which has been accepted by the United States Patent Office.

Persons skilled in the art would know the known forms of torsemide that can be produced using Applicant's process of manufacture as discussed above, as supplemented by the prior art. In respect of the term "if desired" Applicant has deleted said term and substituted it with the term "optionally", "optionally" being an acceptable alternative format permitted in the claims. For example, in *Ex parte Cordova*, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) the language "containing A, B and optionally C" was considered acceptable alternative language because there was no ambiguity as to which alternatives are covered by the claim. A similar holding was reached with regard to the term "optionally" in *Ex parte Wu*, 10 USPQ2d 2031 (Bd. Pat. App. & Inter. 1989). In *Ex parte Wu*, it was stated:

The rejection under 35 USC 112 is based on the Examiner's contention that the term "optionally" in claim 1 does not clearly indicate whether the polyamine is intended to be part of the composition. We have no difficulty determining the scope of claim 1 as drafted. The composition set forth in the claim can consist of the first three components recited or it can include a polyamine as a fourth component. We

therefore do not consider the claims to be indefinite as a result of the claimed optional component.

Furthermore, *Ex parte Cordova*, 10 USPQ2d 1949 (Bd. Pat. App. & Inter. 1989) states:

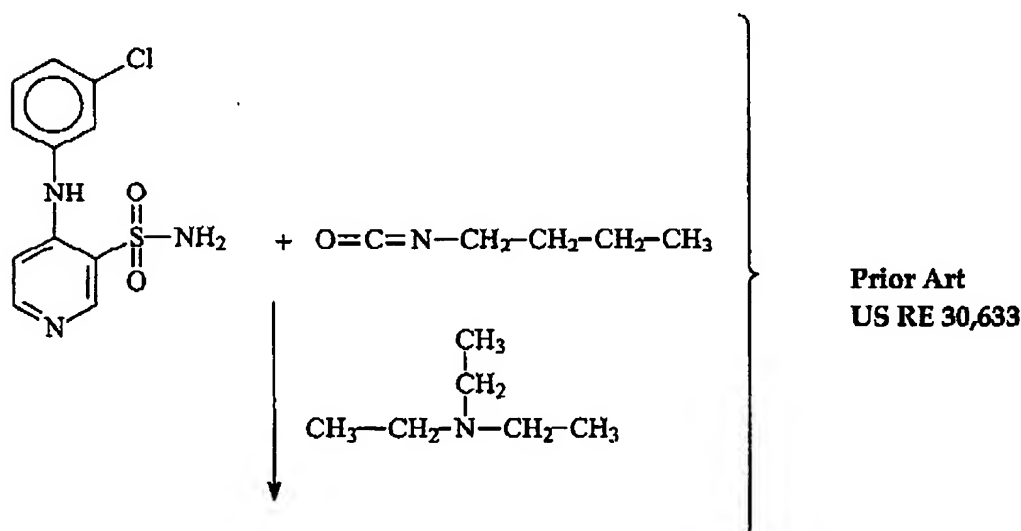
Claims 1, 3, 7, 8, 11, 12 and 15 through 18 stand rejected under the second paragraph of 35 U.S.C. 112 as indefinite. The examiner contends that the use of the term "optionally" is ambiguous, since it is not clear whether the unsaturated aliphatic carboxylic acid is, in fact, encompassed by the claims. The recitation "optionally" denotes that the unsaturated aliphatic carboxylic acid may or may not be employed. It is not apparent, and the examiner has not explained, why the use of such alternative language fails to particularly point out and distinctly claim the subject matter appellants regard as their invention. It is our opinion that the use of the alternative expression "optionally" in the rejected claims does not obfuscate the subject matter appellants regard as their invention. *Ex parte Head*, 214 USPQ 551 (Bd. App. 981). The examiner's rejection under the second paragraph of 35 U.S.C. 112 is, therefore, reversed.

The term "optionally" being fully supported by the application as filed.

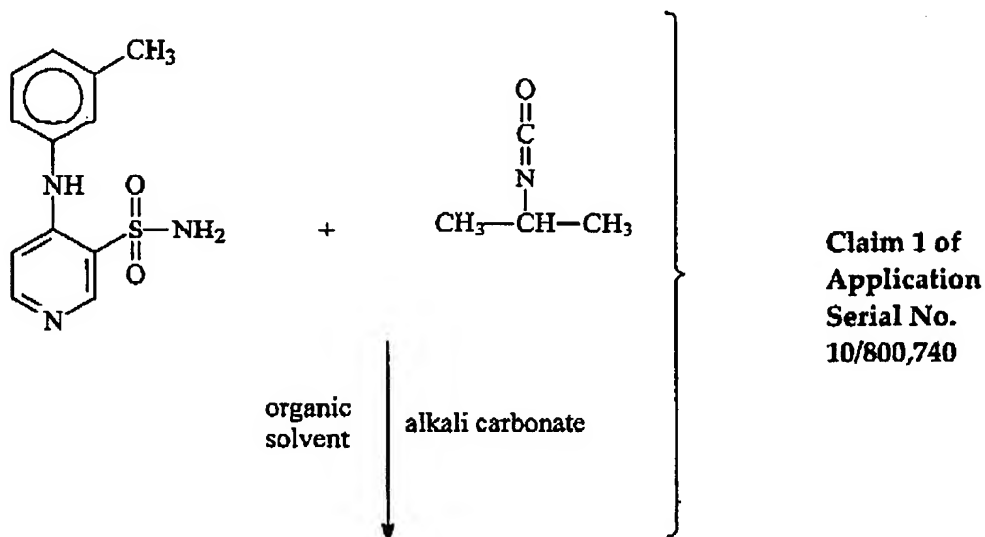
Therefore, in light of the above, Applicant respectfully requests reconsideration of Claims 1, 2, 6-14.

35 USC 102 Rejection

The Examiner has rejected Claims 1, 6-11, 14 and 15 under 35 USC 102(b) as being anticipated by Delarge et al US RE 30,633, namely, column 6, lines 30-42, example 1, section A. Applicant respectfully submits that the Examiner is incorrect. The process described in column 6, lines 30-42, example 1, section A, is as follows:



Whereas, Claim 1 of Applicant's application provides as follows:



It is clear from the pictorial depictions that the principle reactants in the prior art are not the same as in Applicant's Claim 1. Anticipation requires that all the elements of a claim be found in one reference. All the elements of Claim 1 are not found in US RE 30,633. Therefore, there cannot be anticipation of Claims 1, 6-11, 14 and 15 under 35 U.S.C. 102(b). Applicant has discussed extensively the drawbacks of US RE 30,633 at page 2, paragraphs [0006], [0007] and [0008] of the application as filed and Applicant respectfully directs the Examiner to those paragraphs. Thus, reconsideration of Claim 1, 6-11, 14 and 15 is respectfully requested.

Therefore, in light of the submissions presented above, Applicant respectfully requests reconsideration of all the claims currently on file and early allowance of same.

If any questions arise, the Examiner is respectfully requested to contact Applicant's Agent, Marcelo K. Sarkis at (905) 771-6414 collect at the Examiner's convenience.

Respectfully submitted,
IVOR M. HUGHES

Marcelo Sarkis

Marcelo K. Sarkis
Registration No. 37015
Agent for the Applicant
MKS*kdK

Enclosure: Request for One Month Extension of Time